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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,149	08/08/2003	Gerald E. McDonnell	STRSP0119US	3426

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/637,149	MCDONNELL ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 31-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 31-75* is/are rejected.

7)☒ Claim(s) *1, 53, 69* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/2010 has been entered.

Claim Objections

Claim 1 is objected to because of the following informalities: o-benzyl-p-chorophenol is misspelled. It is suggested that the claim reads on a “o-benzyl-p-chlorophenol”; see line 7. Appropriate correction is required.

Claim 69 is objected to because of the following informalities: “moe” is misspelled. It is suggested that the claim is amended to use the word “more”; see line 3. Appropriate correction is required.

Claim 53 is objected to because of the following informalities: it appears that "dodecyl benzyne sulfonic acid" comprises a misspelling. It is suggested that the claim is amended to use "dodecyl benzene sulfonic acid"; see para. 43 of the instant specification, line 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 31-75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising using compositions that inactivate infectious prions for some claimed ingredients (as shown by the prior art), does not reasonably provide enablement for such a method for inactivating infectious prion proteins for compositions comprising all of the ingredients claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. Enablement is considered in view of the *Wands* factors.

Nature of the invention. The claims are drawn to (in part): a method of treating a body which is contaminated with infectious prions, the method comprising one or more phenols and an organic sulfonate, the one or more phenols comprising: o-benzyl-p-chlorophenol; o-phenylphenol; 2,3-dimethylphenol; p-chloro-m-cresol; p-chloro-m-xylanol; 2,4,5-trichlorophenol; or a mixture of two or more thereof; wherein the organic sulfonate may be any one of those listed in claims 40-44; wherein the one or more phenols further comprise those listed in claim 66; and wherein the surfactant comprises those listed in claims 69 and 70.

Scope of the invention. As claimed, the invention is extremely broad encompassing any and all compositions which may widely vary in view of their ingredients (e.g. different phenols, organic sulfonates and surfactants). The compositions are used in a method for inactivating infectious prions on a body.

State of the prior art. Ernst and Race (*J Virological Methods,* 1993) provide a method comprising inactivating prions using compositions comprising glycolic acid, p-tertiary amylphenol, o-benzyl-p-chlorophenol, o-phenylphenol, hexylene glycol and isopropanol, which are some of the ingredients claimed in the instant invention (see p. 196, as discussed below and see instant claims 1, 39, 53 and 56). US Patent No. 6720355 (or "Prusiner") describe inactivating prions using compositions comprising alkyl sulfates, alkyl sulfonates, alkylaryl anionic surfactants, inorganic salts and water at varying pH values, including both acidic and basic (see col. 12-17, as discussed below and see claims including (1, 40, 46-48, 52, 55, 56, 67-70 and 74). Also, see US Patent 5633349 which teaches using sodium lauroyl sarcosinate and C8-C26 alkyl sulfonate in compositions for inactivating prion proteins (col. 3, lines 50+).

However, the prior art does not disclose all of the ingredients claimed can successfully inactivated infectious prions, including (as examples) thymol, cresol derivatives, nitrophenol, hexachlorophene, caffeic acid, triclosan, alpha olefin sulfonate, etc. Note that the prior art describes the infectious prion protein as being extremely resistant to physiochemical inactivation procedures such as heat, radiation, chemical disinfectants and because of its remarkable resistance, it is difficult to inactivate prion (see Yamamoto, J Vet Med Sci, 2001, abstract, cited in IDS).

The prior art describes IFDO as having comparable properties to that of the CJD or scrapie agent, including resistance to proteinase K and trypsin (see Burdon, J. Med. Microbiol., 1989, abstract-attached). The author also notes that the IFDO differs from scrapie in that IFDO is inactivated by ethidium bromide, zinc nitrate, EDTA,

hydroxylamine in the presence of Sarkosyl and under some circumstances by ribonuclease (abstract). Note that according to this publication, the author expresses uncertainty as to what an IFDO is stating: "The chemical and enzymatic evidence points to IFDO containing essential protein, lipid constituents and ribonucleic acid"; p. 155, col. 2, para. 2. In a subsequent publication by this author, the author states that IFDO is a TSE-like agent but only in some ways and that it provides a valid model for investigating the nature of TSE agents (Burdon et al., J. Med. Microbiol., 1996) but it appears that this is only in reference to the ability of IFDO to assemble as a proteinaceous protein (p. 14, col. 2, para. 3), in contrast to a prion model for evaluating structural properties under certain chemical conditions.

Working examples. The working examples are drawn to the effects of IFDO under different chemical conditions. The examples do not provide any correlations of the chemical effects on an IFDO to that of infectious prions and it is unclear how these effects are transferred to the inactivation of an infectious prion. Further, the examples do not actually use an infectious prion protein under different chemical conditions.

Guidance in the specification. The specification provides no guidance regarding the actual structure of an IFDO and how this may be correlated to that of the infectious prions.

Predictability of the art. One of ordinary skill in the art would have to perform prima facie experiments in order to determine if the compounds of the claimed methods are able to inactivate prions at all.

Amount of experimentation necessary. The ordinary artisan would be required to correlate both the structure and function of an IFDO to that of the infectious prion protein in order to determine how the chemical effects to an IFDO correlate to that of the prion protein.

Given the discussion above, it would require undue experimentation for the ordinary artisan to perform the full scope of the method as claimed, particularly those ingredients not identified by the prior art as successfully inactivating prions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 31-40, 45-52, and 55-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of US Patent No. 6720355

(hereinafter as "Prusiner") and Ernst and Race (*J Virological Methods*, 1993). The claims are drawn to (in part): a method of treating a body which is contaminated with infectious prions, the method comprising contacting a body with a composition comprising one or more phenols and an organic sulfonate, the one or more phenols comprising: o-benzyl-p-chlorophenol; o-phenylphenol; or a mixture of two or more thereof; see claim 1.

Prusiner describes a method of using compositions for inactivating infectious prions on infected surfaces, such as medical equipment, food products, blood (col. 1, lines 35+, col. 4, line 30 and instant claims 1, 31-33, 36, 57-59 and 62, in part). The compositions comprise an organic sulfonate, including an alkyl sulfonate (sodium salt) and an alkyl sulfate which was shown to effectively denature prions (see col. 54-55, Ex. 19 and instant claims 1, 40 and 55, in part). Note that the instant specification describes the use of an anionic surfactant which may include an alkyl sulfonate; see para. 47. Thus, Prusiner meets the claim limitations of a composition comprising a surfactant (instant claim 56, in part), an alkylaryl anionic surfactant (instant claims 67 and 68, in part) and wherein the surfactant comprises a sulfonic acid (instant claim 69, in part) and wherein the surfactant comprises an alkyl sulfonate (instant claim 70, line 3, in part). The author also discloses using compositions which are either acidic or basic (alkaline); see col. 3, lines 39+ disclosing a pH of 4.0 or less and a pH of 10 or more and instant claims 46 and 47. A solvent ingredient includes water in varying amounts (col. 12, lines 51+, col. 13-17 and instant claim 48). Inorganic salts in the composition are found in col. 6, lines 60+; see instant claims 52 and 74.

Prusiner does not disclose a method using phenols (including o-benzyl-p-chlorophenol and o-phenylphenol of claims 1, 39 and 56) or a composition further comprising one or more cosolvents (see claims 51 and 73).

Prusiner does not disclose a method wherein at least one phenol has a Log Pc value of at least about 2.5 (claim 45), a method of using a composition wherein the composition is in the form of a concentration which is diluted with water (claims 49 and 71) and a method wherein the concentrate has a total phenol concentration from about 0.1M to about 1.0M (claims 50 and 72).

Prusiner does not disclose a method of treating a body wherein the body comprises a work surface in a hospital or research facility (claims 34 and 60), medical waste (claims 35 and 61), cages used for housing animals (claims 36 and 63) and wherein the method is used to decontamination a disinfection of sterilization system (claims 38 and 64).

Ernst and Race describe methods of inactivating the scrapie agent using different concentrations of LpH, an aqueous and phenolic disinfectant (see abstract and p. 196). This composition comprises o-benzyl-p-chlorophenol, #2-phenylphenol (also called o-phenylphenol), p-tertiary amylphenol, and hexylene glycol (see p. 196 and instant claims 1, 39, 56, 65 and 66). The authors describe using different concentrations of LpH which were made by serial dilutions (p. 196, para. 1). Note that the instant specification describes a cosolvent in para. 45 and such a cosolvent may include hexylene glycol which is found in the LpH composition; thus, claims 51 and 73 drawn to a cosolvent are met by this reference.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Prusiner and Ernst and Race to perform a method of inactivating infectious prions. One would have been motivated to do so in order to make a composition comprising ingredients known to inactivate infectious prions, including alkyl sulfonates, o-benzyl-p-chlorophenol, #2-phenylphenol (also called o-phenylphenol) and hexylene glycol, a cosolvent. There would have been a reasonable expectation of success given the ingredients have been characterized in view of inactivating infectious prions, as shown by the cited art. Also, see MPEP 2144.06 for the following:

I. < COMBINING EQUIVALENTS KNOWN FOR THE SAME PURPOSE
"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Prusiner and Ernst and Race to perform a method of inactivating infectious prions at different concentrations of ingredients in a composition, including at least one phenol having a Log Pc value of at least about 2.5, and further diluting a more concentrated solution with water so that the total phenol concentration is between 0.1M and 1.0M. One would have been motivated to do so for the gain of optimizing results, with the result effective parameter being inactivation of infectious prions at a controlled rate. Note that Prusiner describes using water as a solvent ingredient as discussed

above. There would have been a reasonable expectation of success given the underlying techniques are widely known and commonly use as shown by the applied prior art (e.g. serial dilution of a composition taught by Ernst and Race, as discussed above).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Prusiner and Ernst and Race to perform a method of inactivating infectious prions comprising using the compositions on surfaces or in places wherein infectious prions may be transmitted, including surfaces of a hospital or research facility, medical waste, animal cages, or sterilization systems. One would have been motivated to do so in order to ensure safety against prion transmission or for preventative maintenance. There would have been a reasonable expectation of success given the compositions described by the cited prior art were demonstrated to be effective in inactivating infectious prions.

The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 54 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6720355 (hereinafter as "Prusiner") and Ernst and Race (*J Virological Methods*, 1993-previously cite) as applied to claims 1, 31-40, 45-52, and 55-74 above, and further in view of US Patent No 7252720 (hereinafter as "Foster"-previously cited).

The claims are further drawn to a method of using a composition further comprising brine.

The combined teachings of Prusiner and Ernst and Race disclose a method of treating a body (e.g. surface) which is contaminated with infectious prions, the method comprising contacting the body with a composition comprising one or more phenols and an organic sulfonate, the one or more phenols comprising: o-benzyl-p-chlorophenol; o-phenylphenol; or a mixture of two or more thereof; e.g., see claim 1.

The combined teachings of Prusiner and Ernst and Race do not disclose using a composition comprising brine in the method of inactivated prions. Although Prusiner discloses the use of salts, Prusiner does not disclose using water heavily saturated with salt.

Foster describes the removal of prion infectivity (see whole document). The authors provide that the use of concentrated solutions of salts, such as 2M sodium chloride, is effective in both eluting and completely removing adsorbed prion infectivity (abstract and col. 2, lines 62+). The authors further describe a method of cleaning a reusable substrate via washing the substrate with a salt solution of a concentration of at least 1.0 M (see col. 2, lines 62+-col. 3).

It would have been obvious to one of ordinary skill in the art to incorporate the use of brine in the method taught by Prusiner and Ernst and Race. One would have been motivated to do so because Foster teaches that a high concentration of salt, including sodium chloride, in solution is effective in cleaning a substrate (e.g. medical surfaces). There would have been a reasonable expectation of success given the ingredients, including a high salt solution and phenols, have been characterized in view

of prion removal and inactivation. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6720355 (hereinafter as "Prusiner") and Ernst and Race (*J Virological Methods*, 1993-previously cite) as applied to claims 1, 31-40, 45-52, and 55-74 above, and further in view of US Patent No 7001873 (hereinafter as "McDonnell") and/or US Patent No 5326789 (hereinafter as "Narayanan").

The claims are further drawn to a method of using a composition using water, glycolic acid, dodecyl benzene sulfonic acid and hexylene glycol (see claim 53).

The combined teachings of Prusiner and Ernst and Race disclose a method of treating a body (e.g. surface) which is contaminated with infectious prions, the method comprising contacting the body with a composition comprising one or more phenols and an organic sulfonate, the one or more phenols comprising: o-benzyl-p-chlorophenol; o-phenylphenol; or a mixture of two or more thereof; e.g., see claim 1.

Note that Ernst and Race teach the LpH composition which comprises glycolic acid and hexylene glycol in addition to o-benzyl-p-chlorophenol and o-phenylphenol (p. 196).

Also, note that Prusiner teaches using water as a solvent ingredient as discussed above and SDS or sodium dodecyl sulfate (see title). The authors also teach the use of an alkyl benzene sulfonate (col. 7, line 45).

Prusiner and Ernst and Race do not specifically disclose the use of dodecyl benzene sulfonic acid.

McDonnell teaches using a solution comprising surfactants for the attacking and removing prions from a surface (see abstract). The author teaches the use of the surfactant, dodecyl benzene sulfonic acid (col. 3, lines 12).

Naranayan teaches compositions comprising an anionic surfactant, including SDS or a dodecylbenzene sulfonate (see abstract).

It would have been obvious to one of ordinary skill in the art to further include an anionic surfactant, including a dodecylbenzene sulfonate, in the composition used the method taught by Prusiner and Race and Ernst. One would have been motivated to use this known surfactant as an equivalent to SDS which is comprised in the composition taught by Prusiner. Further, McDonnell teaches its use in a composition for attacking and removing prions from a surface. There would have been a reasonable expectation of success given the underlying techniques are widely known and commonly used (e.g. making a composition requiring a known surfactant) as shown by the prior art. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Zachariah Lucas/
Primary Examiner, Art Unit 1648